

<u>UNITED STATES PATENT AND TRADEMARK OFFICE</u>

Examiner: Not Yet Known

Art Unit: 1615

Re:

Application of:

GREENWALD, Richard B., et al.

Serial No.:

09/823,296

Filed:

March 29, 2001

For:

TERMINALLY-BRANCHED POLYMERIC

LINKERS CONTAINING EXTENSION MOIETIES AND POLYMERIC CONJUGATES CONTAINING

THE SAME

## **INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents Washington, D.C. 20231

June 26, 2001

Docket 1

Sir:

Pursuant to M.P.E.P. § 609 and 37 C.F.R. § 1.56, 1.97 - 1.99, Applicants herewith submit forms PTO-1449, which lists references of which Applicants are aware.

Copies of the references cited in the PTO-1449 forms are included herewith.

This submission does not represent that a search has been made or that no better art exists. While the term "references" is used in citing the U.S. patents called to the Examiner's attention herein, Applicants do not make any admission that each or all of them are "prior art" references within the meaning of the statutory and case law.

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on June 26, 2

ROBERTS BY:

Michael N. Mercanti

Applicants reserve the right to contend, where appropriate, that a patent asserted against any taim of the present application is not prior art under the facts and the law.

Applicants also reserve the right to present appropriate arguments and/or evidence to establish patentability over the references, should one or more of the references be applied against the claims of the present application.

Applicants request that the Examiner independently determine those items which the Examiner would consider the most pertinent of all the references cited herein.

This Information Disclosure Statement is filed within three (3) months of the filing date of this application and before the mailing date of the first Office Action on the merits. Accordingly, this document complies with the requirements of 37 C.F.R. Section 1.97(b). It is respectfully requested that the references cited in the accompanying PTO-1449 Forms be considered and made of record.

No fee is believed to be due. Any deficiency or overpayment concerning this document should be charged or credited to Deposit Account No. 50-0217.

Respectfully submitted,

ROBERTS & MERCANTI, L.L.P.

Michael N. Mercanti

Reg. No. 33,966

ROBERTS & MERCANTI, L.L.P. EDC II
105 Lock Street, Suite 203
Newark, New Jersey 07103
(973)621-0660
(973)621-0660

						Docket Number (Optional)	Α	pplication Number		رر
UNFORMATION DISCLOSURE CITATION  Ose several sheets if necessary)						213.1127-		09/823,296		
						Applicant(s) GREENWALD, R.B., et al.			= O	
JUN 2 8 2001 E						Filing Date Group Art Unit March 29, 2001		roup Art Unit	1613.	3 111
101	W .		<u>\$</u>	<del> </del>	IIS PAT	ENT DOCUMENTS	<u> </u>			
*EXAMINER	& TO	OE AN	<u>*</u>	T	T =			1	299FILING	
INITIAL	78.2		DOCUMENT NUMBER	DATE		NAME	RE	SUBCLASS	IF APPRO	
	A1	U.S	. 5,756,825	05/26/98	SAFAV	Y, A., et al.	JUM	EIVE	04/16/93	<b>3</b>
	A2	U.S	6. 6,020,373	02/01/00	SCHEL	LENBERG, K., et al.	707 2	2001	04/21/97	! 
	A3	U.S	5, 5,919,455	07/06/99	GREEN	WALD, R.B., et al.	10 <sub>1</sub>	<u></u> ≯00	03/20/97	1
	A4	U.S	6. 6,113,906	09/05/00	GREEN	WALD, R.B., et al.		00	12/29/98	3
	A5	U.S	5. 5,643,575	07/01/97	MART	INEZ, A., et al.			10/27/93	<b>,</b>
	A6	U.S	. 5,382,657	01/17/95	KARAS	SIEWICZ, R., et al.			08/26/92	<u> </u>
	A7	U.S	. 5,932,462	08/03/99	HARRI	S, J. M., et al.			05/17/95	5
	A8	U.S	5. 5,433,886	07/18/95	SHERE	SONDY, A.M., et al.			05/07/92	2
	A9	U.S	5, 5,283,339	02/01/94	ARNOI	LD, F.H., et al.			08/05/92	<b>?</b>
	A10	U.S	. 5,454,954	10/03/95	ALFAN	O, N. J., et al.			11/02/94	l
	A11	U.S	5. 5,693,626	12/02/97	SAKSE	NA, et al.			06/02/95	5
					FOREIG	N PATENT DOCUMENTS				
	REF		DOCUMENT NUMBER	DATE		COUNTRY	CLASS	SUBCLASS	Trans YES	lation NO
	A12	wo	95/09883	04/13/95	PCT				1123	1
	A13	ЕР	0 809 996 A2	03/12/97	EUROI	PE				1
			······							
		<u> </u>			OTHER I	DOCUMENTS (Including A	uthor, Title, D	ate, Pertinent Pa	ges, Etc.)	L
KING, H.D., et al., Monoclonal Antibody Conjugates of Doxorubicin Prepared with Branch for Increasing the Potency of Doxorubicin Immunoconjugates, Bioconjugate Chem., 1999, p.						nched Linkers	A Novel	Method		
		A14	lor meressing one rotes	ey of Dozol dole		oconjugutes, Dioconjugute	Circuit, 1777	, pages 217 20		
	OHYA, Y., et al., Synthesis and Cytotoxic Activity Doxorubicin via Ester, Amide, or Schiff's Base Bo			of Conjugates of Monome	thoxy-Poly-	ethylene glyco	l) End-cap	ped with		
		A15	Poadi udicili via Ester, P	amiue, of Schill	3 Dase 19()	nu, Juurnai oi Dioattive at	ia Compani	ie i diymeis, 1	773, pages	) J1 <b>-</b> 00.
EXAMINER				DATE CONSIDERED						
DAY A B 475 D	D. 7	L-1 10 11			C	AL MORD C. 41 COS P.		altation is a state		
			iation considered, whether or of this form with next comm			with MPEP Section 609; Draw	v ane through	citation II not in	conio <b>rmanc</b>	e and not

Form PTO-A820 (als form PTO-1449)

					ATTY DOCKET NO. SERIAL NO. 09/823,2964		•			
INFORMATION DISCLOSURE CITATION					APPLICANT(S) GREENWALD, R.B., et al.			(023,290) C		
The several sheets if necessary)					FILING DATE GROUP		SROUP	<del>- ਨੂ</del>		
JUN 2 8 2007 E					March 29, 200	1	·			
34		N. S. S.		U.S	S. PATENT	DOCUMENTS		<del></del>		0 2 0 E
EXAMINER INITIAL	E TRA		DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING DATE IF APPEROPE	
	A16	U.S	. 5,994,517	11/30/99	TS'0, 1	P.O.P., et al.	<b>D</b> .		1122/96	D
	A17	U.S	. 6,039,931	03/21/00	SCHMI	TT-WILLICH, et al.	ME	CEL.	10/06/94	
	A18	U.S	. 5,693,310	12/02/97	GRIES,	, H., et al.	JUN.		10/09/90	
_	A19	U.S	. 5,679,852	10/21/97	PLATZ	EK, J., et al.	TC	<001	06/02/95	
	A20	U.S	. 5,646,159	07/08/97	WALL,	M.E., et al.		100	07/20/94	
	A21	U.S	. 5,968,943	10/19/99	CAO, 2	Z., et al.			02/25/98	
	A22	U.S	. 5,583,206	12/10/96	snow,	R.A., et al.			11/28/94	,
						500				
				FORE	IGN PATE	NT DOCUMENTS				
	:		DOCUMENT NUMBER	DATE		COUNTRY	CLASS	SUBCLASS	TRANSI YES	ATION NO
<del></del>										
			<del></del>							
						· ,				-
			OTHER DOCUME	NTS (Includin	g Author	, Title, Date, Pertinent I	Pages, Etc.	.)	<b>.</b>	
	BENAGLIA, M., et al., Synthesis of New Poly(ethyleneglycol)s with a High Loading Capacity, J. Org. Chem., 1998, pages 8628-8629.						3,			
		A23								
		CHEN, J., et al., Thiol-Reactive Luminescent Chelates of Terbium and Europium, Bioconjugate Chem., 1999, pages 311-315.					•			
:		•								
EXAMINER				DATE CONSIDERED						
	EXAMINER: Initial if reference considered, whether or not citation is in conformance					Le with MPEP 609; Draw line to	hrough citation	if not in conform	nance and no	ot
considered. Include copy of this form with next communication to applicant.										

Form PTO-A820 (also form PTO-1449)

		F*:	Docket Number (Optional)	Application Number			
			213.1127-	00/823 306			
INF		APIEN DISCLOSURE CITATION (Use several sheets if necessary)	Applicant(s) GREENWALD, R.B., et al.	EN F			
		Total Succession	Filing Date	Group Art Unit			
	JUN	ير 2 8 2001	March 29, 2001	1615 ~			
*EXAMINER	ス	OTSER DOCUMENTS (Including Author, Titl	e, Date, Pertinent Pages, Etc.)	,000 ,000			
INITIAL	TENT &	HINDS J.V., et al., Paramagnetic Oligonucleotide Repeation Enhancement Effects, Bioconjugate Cl	es: Contrast Agents for Magnetic Res hem., March/April 1999, Volume 10, 1	onance Imaging with Proton Number 2, PAGES \$25-158.			
	A25			_			
		YAMASAKI, N., et al., Some Properties of Ricin	D Modified with a Methoxypolyethyle	ne Glycol Derivative, Agric. Biol.			
	A26	YAMASAKI, N., et al., Some Properties of Ricin Chem., 1990, Volume 54, Number 10, pages 2635- GREENWALD, R.B., et al., Drug Delivery System Amine-Containing Compounds, Journal of Medicing Shearwater Polymers Catalog, Inc., Group Three	204U.				
		GREENWALD, R.B., et al., Drug Delivery System Amine-Containing Compounds, Journal of Medica	ns Employing 1,4- or 1,6- Elimination inal Chemistry, 1999, Volume 42, Nur	Poly (ethylene gly/oi) Prodrugs of nber 18, pages 3657-3667-			
	A27			JUNZOVED			
		Shearwater Polymers Catalog, Inc., Group Three	A - Active Esters, page 13, 2000.	70 7001			
	A28			<sup>3</sup> /200			
		GREENWALD, R.B., et al. ,Poly(ethylene glycol) Critical Reviews in Therapeutic Drug Carrier Sys	Confugated Drugs and Progrugs: A C	comprehensive Keview.			
	A29						
		WILLIAMS, M.A., et al., Synthesis of Enantiome L-Phenylalanine as the Educt for Sunstituion at the	rically Pure Diethylenetriaminepenta he Central Acetic Acid., J. Org. Chen	acetic Acid Analogues. 1., 1993, Volume 58,			
	A30	pages 1151-1158.					
		Shearwater Polymers, Inc. Catalog, Polyethylene	Glycol Derivatives, Star Pegs and Bra	nched Pegs, 1997-1998			
	A31						
····		Shearwater Polymers, Inc., Quarterly Newsletter,	March 1998, Number 1				
	A32						
		SAKSENA, Anil K., et al., Concise Asymmetric R Imide Enolates: Key Intermediates Towards Synt Tetrahedron Letters, Vol. 37, No. 32, pages 5657	hesis of Highly Active Azole Antifung	drofurans Via Chiral Titanium als SCH 51048 and SCH 56592,			
	A33	Tetraneuron Letters, Vol. 37, No. 32, pages 3037	-3000, 1770.				
		TWYMAN, L.J., et al., The Synthesis of Water Systems, Tetrahedron Letters, Volume 40, 1999,	oluble Dendrimers, and their Applica pages 1743-1746.	tion as Possible Drug Delivery			
	A34						
	CERNY, L.C., et al., A Potential Blood Substitute From A Tetronic Polyol And A Modified Hemoglobin, & Immob. Biotech., Volume 20, No. 1, pages 71-93, 1992.						
	A35						
_		GREENWALD, R.B., Oncologic, Endocrine & Mo Polymeric Conjugates, Exp. Opin. Ther. Patents,	etabolic; Drug Delivery Systems: Anti Vol. 7, No. 6, pages 601-609, 1997.	cancer Prodrugs and their			
	A36						
EXAMINER	1	1	DATE CONSIDERED				
EXAMINER: 1	nitial if	citation considered, whether or not citation is in conforman	ce with MPEP Section 609: Draw line throu	gb citation if not in conformance and not			

considered. Include copy of this form with next communication to applicant.

		13.			
			Docket Number (Optional)	Application Number	
<u>,</u>	10	E V	213.1127-0	09/82 3596	
INF	DRMA	TION DISCLOSURE CITATION	Applicant(s)	<u> </u>	
7	_	(Use several sheets if necessary)	GREENWALD, R.B., et al.	유 는 <b>M</b>	
Ì (	JUN 2	8 2001 H	Filing Date Moreh 20, 2001	Group Art Unit	
\_	-		March 29, 2001	1645 0	
*EXAMINER	EN.	THER DOCUMENTS (Including Author, Title MONFARDINI, C., et al., A Branched Monometh 1995, Volume 6, pages 62-69.	le, Date, Pertinent Pages, Etc.)	160	
INITIAL	4 1	MONFARDINI, C., et al., A Branched Monometh	oxypoly(ethylene glycol) for Protein	Modification, Bioconjugate Chem.	
		1995, Volume 6, pages 62-69.	B3 3	72.	
	A37			17 D	
	-	RANGANATHAN Detal Synthesis of Totally	Chiral Multiple Armed Poly Clu an	d Poly Asn Scaffoldings on	
		RANGANATHAN, D., et al., Synthesis of Totally Bifunctional Adamantane Core, Tetrahedron Lett	ters, Vol. 38, No. 7, pages 1265-1268,	1997.	
	A38				
				_	
				TC 1700	
				**C^.	
				J/1 5/1/2	
			,	7- 5920 U	
				10 (0)	
				7>-	
				''(00	
			<u></u>		
		-1			
			<u></u>		
EXAMINER			DATE CONSIDERED		
			1		
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					